

## **Office Action Summary**

The Examiner has rejected claims 41-43 under 35 U.S.C. 102(b) as being anticipated by Bessler, et al. – 5411508 (**D1**)

The Examiner has rejected same claims 41-43 under 35 U.S.C. 102 (b) also as being anticipated by Wilk, -5330486 (**D2**).

In view of the following remarks, the Examiner's rejections under 35 U.S.C. 102(b) as to D1 and as to D2 are respectfully traversed

### **§102(b) Rejections – Bessler- US 5 411 508 (D1)**

Independent claim 41 and its depending claims 42 and 43 are under this item.

Claim 41 discloses a method for realizing any variety of circular anastomosis (i.e. end to end, end to side, side to end or side to side) by the means of a flexible annular stapler, in any chosen area predefined by a surgeon, between two different hollow organs or between segments of the same hollow organ. This joining may be applied to any of a number of hollow organs, including any part of the digestive tube and organs external thereto, such as the bronchial tree, the urinary bladder and urinary tree, gallbladder and biliary tree ..., and not only to the colon. The illustrations of colon's surgical procedures in present specification are given just by way of examples. It is emphasized that neither of the parts to be joined need to be naturally tubular near the joint (like the cut end of the intestines), but may, for example, be a wall of the respective organ. What is common to all cases described in the claims of present specification (including claim 41!), is that there is conceptually defined for each of the two parts; a plane and an annular area thereon, the two annular areas being essentially congruent. During the joining operation, the two annular areas are brought together and conceptually combined into one annular area, over which the stapling and eventually the anastomosis take place. In the case that one of the parts is tubular at the joint, as in end-to-end or end-to-side anastomosis, (in which case that part is always cut across) the defined plane is transverse and at a short distance away from the plane of cutting. In the case that one of the parts presents an outer face of a wall at the joint, as in a side-to-end or side-to-side anastomosis, the plane is essentially at the face. Furthermore, in the case of a tubular part, there is an inherent opening through it at the defined plane and interior to the annular area (which opening is, in some procedures, not always initially accessible to the stapler, or, in some other procedures, may be intentionally closed off before the stapler reaches it). On the other hand, in the case of a part being joined at its wall, there is no such initial opening and, if required by a particular procedure (e.g. for insertion of part of the stapler thereto), a suitable opening has to be cut through the wall, interior to the annular area. Of course and as the raison d'être, after the end of the procedure there remains in all cases a clear opening through both parts.

Claim 41(and its depending claims 42,43) describes hence, a multitude of surgical situations finding expression in as much surgical procedures.

Figures 11, 12 and 14 as well as the appending explanations to those figures (page 24, line 17 – page 26, line10 and page 27, line8 – page 28, line 2) in present specification, are few examples of those surgical situations and for which surgical procedures are described. These latter are realizable either under open or closed surgery (as clearly showed in those figures and stated in page 24, lines 3-5 of present

specification) even though that claim 41, was limited (in precedent amendment) to closed surgery only in view of expediting the prosecution.

Examiner's rejection as to independent claim 41 and its depending claims 42 and 43 is therefore, respectfully traversed.

Bessler discloses a flexible annular stapler with specific technical characteristics with the object of overcoming the limitations of the rigid annular stapler version in open surgery conditions (See chapter "Background of the invention" in D1).

Bessler et al. give in column 14 lines 3-46 an example of use of their stapler.

Contrary to applicant's contention, the Examiner considers that "Bessler –by that example- clearly discloses a **method** of use of the device". However, despite that, still remains a huge gap between the supposed "method" of Bessler et al. and the method disclosed in claim 41. What is precisely described by Bessler et al. is a surgical procedure comprising the following:

- a) Realizing a large opening of the abdomen in open surgical conditions, thus "**using different, invasive surgical tools**".
- b) Resecting a diseased colon portion by "using different, invasive surgical tools, leaving two unjoined sections of tubular colon". (*terms quoted from Bessler*)
- c) Extracting manually the diseased colon portion through the wide opening of the abdominal cavity.
- d) Inserting transanally the Bessler's flexible annular stapler such that the anvil is placed in the proximal section of the resected colon and the stapling head is placed in the distal section.
- e) Closing at least partially, the open ends of the proximal and distal sections.
- f) Operating said stapler, thus forming an end-to-end anastomosis.

Clearly this surgical procedure in D1 cannot be considered as an anticipation as to claim 41 of present applicant. Neither the conditions in which the procedure is realized are same (traditional open surgery versus laparoscopic conditions), nor the obligation to resect preliminarily a diseased portion is same [the method of claim 41 can be realized even in procedures necessitating just an anastomosis without any resection and when resection is necessary it can be taken at different stages of the procedures (claim 43); see for example Figures 12 and 14~~Y~~claim 43], nor the necessity of opening the abdomen for extracting the resected portion is same, nor even more the limitation to end-to-end anastomosis is same (the type of anastomosis is adapted to the surgical needs in claim 41).

This description in D1, could however, seem like **one** of the examples given in present specification in view of illustrating one of the surgical procedures described in claims 41-43. It concerns Fig.11 of present application. Nevertheless, the case illustrated in Fig.11 and the appending explanations to that figure (page 24 lines 17-22 in present specification) shows that the surgical procedure of Fig.11, is realized under closed surgery with laparoscopic instrumentation and without any "opening" of the abdomen. The resected segment of colon being placed in a bag and removed through the distal portion of colon or through a suitable minimal abdominal incision (see Fig. 11).

In summary: Independent claim 41 and its depending claims 42 and 43 - as already said- describes a multitude of surgical procedures realizable either under open or closed surgery. The surgical procedure described by Bessler could have been included as one of the numerous possibilities offered by said multitude of surgical procedures. Nevertheless, this possibility has been excluded while limiting claim 41 to method for joining of hollow organs realized under closed surgery conditions, using laparoscopic or thoracoscopic techniques and instrumentation. Consequently to that limitation, other inventive possibilities –under open surgery- have been lost from protection.

Further, the Examiner states that Bessler “clearly discloses the (above) procedure being performed laparoscopically or closed”.

Bessler et al. roughly approach (tackle) the laparoscopic surgery by raising a possibility of using (one embodiment of) their flexible stapler in laparoscopic (closed) conditions. However, they never show neither disclose how, nor (moreover) describe any surgical method to use in such conditions. It is evident that it's not sufficient to claim for something we can do, without doing or showing how to do it unless it's something evident. “Saying is one thing, doing another”. The Applicant therefore, respectfully disagrees with the Examiner as to consider the following quotation from D1 (column 15 lines 45-53):

*“By providing a gastrointestinal stapling device having a long flexible tube (on the order of about 90 cm) virtually all colon resections could be performed through the rectum and laparoscopically, with minimal invasive surgery. In addition to colon resection, the gastrointestinal stapler could allow laparoscopic esophageal, stomach, proximal and distal small bowel and possibly biliary anastomosis to be performed.”*

as if Bessler “clearly discloses the procedure being performed laparoscopically or closed”.

One could retort to obviousness under 35 USC § 103 (a). However, the above assertion of D1 (col. 15,lines 45-53) cannot be reasonably viewed as complying with that USC paragraph with which the Examiner is certainly acquainted. It is simply reminded that conditions of closed surgery in which the abdomen (or chest) spaces are closed, (precluding surgeon's hands from working inside those spaces) differs from the conditions of open surgery, in which the abdomen (or chest) spaces are opened letting (allowing) the hands of the surgeon working in. Bessler et al. never disclose how to surmount and solve the problems encountered in closed surgery.

#### **§102(b) Rejections – Wilk- US 5 330 486 (D2)**

The Examiner has rejected the previously discussed independent claim 41 and its depending claims 42 and 43 as being anticipated also by Wilk in D2. Examiner's rejection as to these claims is also respectfully traversed.

Contrary to Bessler in D1, Wilk in D2 does disclose methods for joining hollow organs in laparoscopic conditions. However, independent claim 41 and its depending claims 42 and 43 still remain not anticipated by Wilk. Neither the methods disclosed by Wilk nor the means (multiples devices) used by Wilk for realization of those methods are same or comparable.

Wilk disclose in D2 several anastomosis forming means in laparoscopic conditions (entitled in his application “associated instruments”). These means comprises a linear anastomosis stapling device combined with an endoscope, a purse-string forming device, an endoscopic surgical assembly connected to an anastomosis forming device, an endoscopic surgical assembly comprising a flexible anastomosis forming device inserted through an expandable biopsy-type channel of a sheath which also encloses an endoscope, a magnetic anastomosis forming device, and more... Yet, it's surprising that the term “annular” or “circular” stapler is never mentionned in D2.

**FIG. 9** in D2 represents (quoted from D2) -“a schematic side elevational view of a resected bowel section, showing a step in the performance of an anastomosis in accordance with (D2) invention”. In that figure, a stapling device looking like a flexible annular stapler is shown inside a tubular organ. However, the appending description to this figure specifies that the device concerned is a “flexible anastomosis-forming device 150” described in figure 7 ( and whose appending explanations, here again, do not specify as being an annular or circular stapler having two round jaws).

Nevertheless, even if claiming the obviousness for the stapler of fig. 9 as being a “flexible annular stapler having two interacting and possibly invertible round jaws” which are the terms of step (a) in applicant's claim 41; yet we're face to one surgical procedure (as in Bessler case) comprising a first step in which a colon resection must take place, and in which an end-to-end anastomosis is compulsory, contrary to the multitude of surgical procedures that claim 41 (and its depending claims 42-43) of present application offers. Please see also the precedent argumentation about Bessler's case in D1.

Finally, applicant has carefully studied the supports given by the Examiner as grounds to D2 anticipation. Respectfully, these latter, have been found of weak pertinence in view of the subject matter of the applicant's claims in concern (claims 41-43). Indeed: -col.3, lines 20-68: refer to a linear device inserted into an expandable biopsy-type channel of a fiber optic endoscope assembly. The relation between this device and the device used in the rejected claims 41-43 couldn't be found.

-col.5, lines 15-32: are concerned with a laparoscopic method comprising “insertion of stapling jaws through a laparoscopic trocar sleeve disposed in abdominal wall of the patient”. The rejected claims 41-43 do not deal at all with insertion of jaws through trocar sleeves.

-col.6, lines 40-65: refer to a method previously discussed in relation with **FIG.9** by using a specific instrument to Wilk, for looping a purse-string type suture laparoscopically.

-col 13, lines 8-34 : refer to a combined procedure illustrated in **FIG.10** of D2. The contentance of this figure is clearly out of relation with the methods rejected in claims 41-43. It deals with anastomosis by a combination of endoscopes and two separate stapling members: one introduced transrectally and the other through the abdominal wall of patient.

-col. 14, line 67- col.15, line 35: deal with **FIG. 12** of D2 and refer to two separate stapling members in a specific method to Wilk. This method as well, has no relation with the methods of claims 41-43 to present applicant.

-col.16, lines 41-49: deal with **Fig. 17A** in D2 using magnetic forces which are out of the scope of present specification.

**FIG. 11** "is a partial schematic view of intestinal organ segments connected to one another in an anastomosis procedure in accordance with (D2) invention, showing a step subsequent to that illustrated in FIG. 10". (terms quoted from D2). FIG. 10 is as already said a clearly different method from the one described in applicant's claim 41.

In view of the discussion above, applicant submits that claims 41-43 were not anticipated neither by D1 nor by D2. However, the Examiner made his last office action, final. Applicant has therefore, in order to expedite the prosecution and avoid the long procedure of appeal, chosen to amend the litigious claims 41-43.

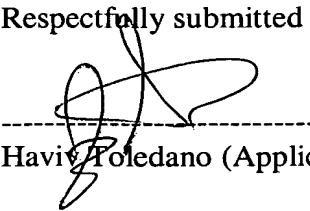
Specifically:

- Independent claim 41 has been limited to a method in which the insertion of the two round jaws of the annular stapler is effected through the mouth of the patient. Support for that can be found in the specification on page 30, lines 3-4.
- Claim 42 depending on claim 41, has been replaced by claim 42 (amended). Claim 42 (amended) still depending on claim 41, introduces another specific feature of the flexible annular stapler, namely a dilating balloon that does not exist in prior arts D1 and D2 such as to sharpen the differences. This dilating balloon offers facilities in realization of the method described in the claim. Support for this feature and the facilities it offers can be found in the specification on page 16, line 24—page 17, line 2; on page 19, lines 10-15; on Fig. 5A; Figures 7 and 8.

Finally, claim 43 (amended) has been made depending on the previously discussed claim 42 (amended).

In view of the above amendments and remarks it is respectfully submitted that present specification is now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted

  
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